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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the implementation of contingency plans and simulation exercises for the prevention, control and eradication of transmissible animal diseases

(Text with EEA relevance)

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concerning the implementation of contingency plans and simulation exercises for the prevention, control and eradication of transmissible animal diseases

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') [1] and in particular Articles 43, 44 and 45 thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

Whereas:

(1) Regulation (EU) 2016/429 lays down rules on the prevention and control of transmissible animal diseases, including those affecting animals and humans, and provides for measures on disease awareness, preparedness and response.

(2) Article 43 of that Regulation provides for the Member States to draw up and maintain contingency plans to ensure disease awareness and preparedness, and to enable a rapid and effective response across the Union to outbreaks of category A diseases referred to in Article (1), point (1) of Commission Implementing Regulation (EU) 2018/1882[2] and emerging animal diseases.

(3) Contingency plans must ensure adequate allocation of resources and specify command structures at national, regional and local level, where possible, that are applicable across multiple category A diseases, regardless of the specific disease agent involved. They must cover general support functions such as communication, logistics, human and material resources, as well as preparedness and control measures applicable across multiple category A diseases.

(4) Article 43 also requires that the Member States draw up, and keep up to date, where necessary, detailed instruction manuals. Instruction manuals refer to and describe the operational instructions and procedures to be implemented in the event of an outbreak of a category A disease, to control and eradicate the disease. Instruction manuals contain documents that provide detailed technical guidance and procedures for listed terrestrial and aquatic animal diseases. They cover aspects such as disease procedure for notification, diagnostic criteria and capacities, epidemiological enquiries, establishment of the restricted zones and control measures to be applied in the restricted zones

[1] OJ L 84, 31.3.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/429/oj.
[2] OJ L 308, 4.12.2018, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2018/1882/oj.

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including derogations, and vaccination plan, where applicable, culling and disposal, cleaning and disinfection, and repopulation.

(5) Contingency plans should include detailed instruction manuals for each category A disease. Detailed technical guidance on the implementation of control measures is indispensable for a harmonised and efficient response to outbreaks. It is therefore necessary for the competent authorities to develop and maintain instruction manuals describing operational procedures for each category A disease, including technical forms, checklists and protocols. To ensure a common understanding and uniform implementation of these control measures throughout the Union, it is necessary to define the terms “contingency plan” and “instruction manual”.

(6) Article 43 of Regulation (EU) 2016/429 requires Member States to establish a chain of command within the competent and other public authorities. A well-defined chain of command ensures an effective and coordinated decision-making process. It shall comprise all relevant levels and the roles and responsibilities of personnel, groups and other stakeholders must be clearly defined. This regulation establishes harmonized rules regarding the organization, reporting structures and communication channels within the chain of command.

(7) Since the management of animal health emergencies requires coordination across multiple sectors and administrative levels, it is necessary to establish procedures for cooperation among competent authorities including those responsible for public health, environment, wildlife, law enforcement and civil protection. Such cooperation should also extend to other Member States and, where appropriate, to neighbouring third countries.

(8) In order to ensure the effective implementation of contingency plans, it is necessary to define the operational structures to be activated in case of an outbreak, in particular the disease control centres and the operational expert groups. The organisation, responsibilities and coordination mechanisms of those structures should be clearly established in advance and set out in this Regulation.

(9) Article 45 of Regulation (EU) 2016/429 requires Member States to organise simulation exercises to test contingency plans. The simulation exercise should be organised at appropriate intervals to verify the functionality of the contingency plans, considering different scenarios including worst case scenarios and involvement of neighbouring countries (other member states and where applicable third countries). This Regulation sets out harmonised rules for the planning, implementation and evaluation of such simulation exercises.

(10) In order to ensure that all concerned stakeholders involved in disease prevention and control are adequately prepared, the competent authorities should provide them with regular and targeted training. Such training should be based on the roles and responsibilities defined in the contingency plans and should be repeated at appropriate intervals.

(11) In particular, and in accordance with Article 10 of Regulation (EU) 2016/429, operators shall have sufficient knowledge of animal health, including disease prevention, biosecurity and control measures. To ensure effective implementation of this obligation, operators keeping animals of listed species should have basic instructions in place and ensure that personnel are trained accordingly.

(12) Preparedness planning is an important element of contingency planning and should be based on a sound assessment of epidemiological risks. It is therefore necessary for

Member States to carry out structured and regularly updated risk assessments covering likely and worst-case scenarios for each category A disease, taking into account relevant scientific opinions and international standards. To ensure the uniform implementation and coherent preparedness planning across the Union it is necessary to lay down harmonised rules in this Regulation.

(13) To maintain their effectiveness and relevance, contingency plans and instruction manuals should be regularly reviewed and, where necessary, updated. Such review should take into account the lessons learned from disease outbreaks, simulation exercises, and new scientific or legislative developments and be at the frequencies and the formats set out in this Regulation.

(14) To ensure the uniform implementation of Articles 43 and 45 of Regulation (EU) 2016/429, it is necessary to lay down detailed rules on the format and minimum content of contingency plans and instruction manuals. This Regulation therefore harmonises the organisation of the chain of command, the definition of roles and responsibilities of all persons and groups involved, and the procedures for cooperation among competent authorities at all administrative levels, including international cooperation. The detailed structure and minimum content of contingency plans and instruction manuals are set out in the Annexes to this Regulation, reflecting the provisions of its articles.

(15) Wild animals of listed species could also be affected by category A diseases. Control measures for those wild animals are essential in preventing the spread of the diseases and in ensuring their control and eradication. As for diseases occurring in kept animals, the competent authority should consider control measures for diseases in wild animals as part of the contingency plans provided for in this Implementing Regulation.

(16) Some listed category A diseases may pose a significant threat to public health. The effective management of such category A diseases with a zoonotic potential requires a One Health approach involving close cooperation between the competent authority and public health authorities. Therefore, it is essential to establish mechanisms for effective collaboration, communication and exchange of information between these bodies as part of the contingency plan in this Regulation.

(17) In addition, Member States have contingency plans for animal diseases in place in accordance with the legislation applicable prior to entry into force of Regulation (EU) 2016/429. It is appropriate to give Member States a certain period of time to adjust their plans and operational procedures with the new provisions in this Regulation.

(18) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

Section 1 – General provisions

Article 1

Subject matter and scope

1. This Regulation lays down implementing rules pursuant to Article 43 and Article 45 of Regulation (EU) 2016/429 concerning:

   (a) the contents, maintenance, implementation, review and update of contingency plans;

(b) development of instruction manuals for the prevention, control and eradication of category A diseases and, where appropriate, emerging diseases in kept and wild terrestrial and aquatic animals ('animals');

(c) contingency plans implementation phases;

(d) chain of command;

(e) coordination with other public authorities;

(f) operational structures for the implementation of contingency plans;

(g) the organisation, conduct and evaluation of simulation exercises.

2. The contingency plans and instruction manuals referred to in paragraph 1 shall apply to:

(a) Category A diseases referred to in Article (1), point (1) of Commission Implementing Regulation (EU) 2018/1882[3];

(b) Emerging diseases as defined in Article 4, point (22), of Regulation (EU) 2016/429.

Article 2

Definitions

(1) 'contingency plan' means a comprehensive and regularly updated document, which, on the basis of probable emergency disease scenarios, defines the suitable response mechanisms to the emergency that will allow the disease to be controlled and eradicated in the most rapid and cost-effective way.

(2) 'instruction manual' means a technical document that provides detailed operational guidance and procedures on how control and eradication measures should be implemented for a specific category A diseases including technical forms, checklists, and technical protocols.

Section 2 – Contingency plans

Article 3

Contingency plans

1. Member States must develop and maintain national contingency plans including multiple scenarios applicable to category A diseases and, if necessary, emerging diseases.

2. The contingency plans referred to in point 1 shall:

(a) be prepared in advance and be ready at the time of suspicion or confirmation of an outbreak of a category A disease in terrestrial or aquatic animals;

[3] OJ L 308, 4.12.2018, p. 21, ELI: http://data.europa.eu/eli/reg_impl/2018/1882/oj.

(b) be readily applicable in case of suspicion or confirmation of emerging diseases to ensure an effective response in a timely manner.

3. The competent authority shall ensure that contingency plans include at least the elements contained in Annex I and comprise of implementation phases set out in accordance with Annex II.

4. When drafting, reviewing, updating or supplementing the contingency plans the competent authority should consult members of the operational expert groups and concerned stakeholders.

5. The contingency plans shall be reviewed and, where necessary, updated as referred to in Article 11 of this Regulation.

Article 4

Chain of command

1. The central competent authority shall establish a chain of command for the implementation of the contingency plans in accordance with the administrative and political structures of the concerned Member State.

2. The chain of command shall comprise all relevant levels, depending on the division of competencies and responsibilities in the respective Member State and on the size and administrative divisions of the Member State concerned. Each level shall have clearly defined responsibilities during each of the implementation phases of contingency plans.

3. Within the chain of command, the competent authority shall identify the following:

(a) who has the authority and responsibility to make decisions at each level;

(b) the roles and responsibilities of all persons or groups involved in disease response, including veterinarians, operators, animal professionals, public authorities at all levels, and other relevant persons or stakeholders concerned;

(c) the reporting structure, specifying who reports to whom and the frequency and modalities of each reporting step;

(d) the communication channels to be used to disseminate internal and external information and the persons or groups responsible, including emergency contact procedures.

4. All actions undertaken in the context of the chain of command shall be traceable, and those responsible shall be held accountable for their decisions and actions.

Article 5

Cooperation with other authorities

1. The contingency plan shall establish procedure for cooperation between the competent authorities and other authorities or concerned stakeholders in accordance with point 2 (b) of Article 43 of Regulation (EU) 2016/429, with:

(a) authorities responsible for public health;

(b) authorities responsible for wildlife, environment, civil protection, law and enforcement;

(c) other operational partners;

(d) stakeholders required to ensure a coordinated response;

(e) neighbouring countries.

2. For category A diseases posing a zoonotic risk, the competent authority shall cooperate with public health authorities, regarding national preparedness and response plans for public health threats and the Union Prevention, Preparedness, and Response Plan as specified in Article 5 of Regulation (EU) 2022/2371.

3. In the contingency plans referred to in Article 3(1) this cooperation must, as relevant, make reference to:

   (a) memoranda of understanding;

   (b) the planning of joint exercises;

   (c) interagency protocols;

   (d) communication protocols, and exchange of information;

   (e) procedures for the liaison with military and civil protection.

Section 3 – Operational Structures

Article 6

Disease control centres and operational expert groups

1. The competent authority shall assign the roles and responsibilities to the different disease control centers in accordance with the administrative organization of the Member State and on the phase of implementation of the contingency plan.

2. The competent authority shall designate and nominate persons to be included in the operational expert groups, as referred to in the contingency plan.

3. The competent authority, or competent authorities at the regional level, shall establish the necessary structures and ensure the availability of sufficient resources for the functioning of disease control centers at various levels and for the operational expert groups.

4. In the event of confirmation of an outbreak of a category A, or emerging disease, the competent authority shall immediately activate:

   (a) a functional central disease control centre;

   (b) regional and local disease control centres, as appropriate;

   (c) operational expert groups for the specific category A disease or emerging disease concerned.

5. The competencies and roles of the disease control centres and the operational expert groups in assisting the competent authority are set out in Annex III.

Article 7

Instruction manuals

1. The competent authority shall, as a part of the contingency plan, develop, keep up to date, and, where relevant, amend or supplement detailed instruction manuals to set out the operational instructions and procedures to be implemented in the event of outbreaks of category A diseases or emerging diseases.

2. The instruction manuals referred to in paragraph 1, shall include at least the elements listed in Annex IV to this Regulation.
3. The competent authority shall review instruction manuals shall be reviewed and, where necessary, update as in accordance with Article 11 of this Regulation.

Section 4 – Simulation Exercises and Training

Article 8

Simulation exercices

1. Simulation exercises referred to in Article 45(1) of Regulation (EU) 2016/429 shall be conducted in one or more of the formats as a tabletop, drill, functional, or full-scale exercise, and as listed in Annex V, as appropriate to the outcomes of the risk assessment.
2. The competent authority shall ensure that at least:
   (a) one simulation exercise is organised every three years at national level;
   (b) one simulation exercise is organised every three years at regional or local level.
3. The category A diseases targeted in each simulation exercise may vary, provided that the exercise addresses:
   (a) certain sections of the contingency plan that are common to all category A diseases, and
   (b) category A diseases relevant to the current epidemiological situation of the Member State and neighbouring countries, or the result of a risk assessment carried out by the competent authority.
4. Simulation exercises shall be organised jointly and carried out in cooperation with neighbouring Member States or third countries, according to the outcomes of the risk assessment.
5. Simulation exercise shall be documented and used to review and, where necessary, used to update the contingency plan according to Article 11 of this Regulation.
6. The competent authority of certain Member States may decide not to organise simulation exercises at the interval indicated in point 2 (a) and (b) for certain category A diseases where:
   (a) the Member State participates in a joint simulation exercise organised pursuant to paragraph 4 that respects the interval referred to in point 2(a) or (b) and the addresses the elements referred to in point 3;
   (b) the disease has occurred for the first time in its territory and the contingency plan has been consequently implemented in practice;
   (c) the disease has re-occurred or remains present in its territory and the contingency plan is being regularly implemented.

Article 9

Training

1. The competent authority shall provide training and material to raise awareness to all authorities and stakeholders referred to in Article 5 (1) as described in the contingency plans of the Member State concerned.

2. The training referred to in paragraph 1 shall be:
   (a) tailored to the roles and responsibilities of the stakeholders;
   (b) repeated at least every three years and after any significant revision of the contingency plans;
   (c) documented.
3. Member States that adopt or update their contingency plans in accordance with this Regulation shall ensure that initial training for all authorities and stakeholders identified in those plans is organised within 12 months from the date of adoption or update.
4. Subsequent training shall follow the frequency established in paragraph 2 point (b).
5. The contingency plan must be accessible to all relevant stakeholders to raise awareness, clarify their roles, and support adequate preparation. However, sections not directly relevant to their preparation may be withheld.

Section 5 – Preparedness and Risk Assessment

Article 10

Preparedness and risk assessment

1. To inform the contingency plan, the competent authority shall carry out structured risk assessments for category A diseases including likely scenarios for each category A disease, potential outbreaks in wild animals and worst-case scenarios.
2. The risk assessment shall be:
   (a) disease-specific and proportionate to the epidemiological situation in the concerned Member State, in the neighbouring countries and other countries that may pose a risk;
   (b) updated at least once every **three years**, and more frequently in case of significant changes in disease epidemiology, trade patterns, or relevant veterinary infrastructure;
   (c) carried out with other Member States with comparable risk profile, where relevant.
3. The outcomes of risk assessments shall guide the development and revision of national contingency plans and instruction manuals, the identification of disease-specific preparedness needs, the design and execution of training and simulation exercises, the periodic review and updating of all emergency preparedness tools.
4. The competent authority shall establish mechanisms to ensure that the risk assessment referred to in paragraph 1 takes into account:
   (a) the international standards;
   (b) the scientific evidence for the relevant category A disease;
   (c) the risk assessment done by other Member States with comparable risk profile.

Section 6 — Review and Updating

Article 11

Review and update

1. The competent authority shall regularly, but at least every three years, review and, when necessary, update or supplement the contingency plans and instruction manuals, taking into account implementation experiences, simulation exercises outcomes, and the evolution of the epidemiological situation of category A diseases and emerging diseases.
2. The competent authority shall review and, when necessary, update or supplement the contingency plans within one year after the completion of a simulation exercise or the recovery period after the implementation of a contingency plan, or relevant instruction manuals, for the occurrence of category A diseases in its territory.
3. The review shall consider the following aspects:
   (a) organizational or structural changes;
   (b) updated risk assessments;
   (c) new legislative or scientific developments;
   (d) lessons learned from outbreaks and simulation exercises.
4. The competent authority shall update the contingency plan in accordance with the recommendations obtained during the review.
5. The review shall be documented.

Section 7 — Final and Transitional Provisions

Article 12

Entry into force and entry into application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from [date].

Member States must align all existing contingency plans with this regulation by…..

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN